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PEPFAR Technical Guidance in Context of COVID-19 Pandemic

April 1, 2020 Updates

Pediatric ARVs

What are the recommendations for pediatric MMD in the setting of COVID-19?

Programs should make every effort to supply children and adolescents living with HIV (CLHIV/ALHIV) initiating and refilling ART with a 3-month supply of ARVs for those who weigh < 20 kg and a 6-month supply for those who weigh 20+ kg. The caregiver should be allowed to pick up the child's medication without bringing the child, unless the child needs a clinical visit. For children requiring Cotrimoxazole, a 3-6-month supply should be provided at the same time as ARV pickup. For children starting a new medication, administration of the first dose should be demonstrated and administered in clinic, particularly LPV/r-based formulations (liquids, pellets, granules, and 100/25mg tablets). Phone or electronic follow-up for pediatric clients (within 3-4 weeks) should be emphasized and include assessment of medication dosing and administration.

HIV-exposed infants should be given the greatest quantity of infant prophylaxis, both ART and cotrimoxazole as possible to last until the next immunization or EID testing appointment.

Our stock of LPV/r 40/10 pellets and granules is inadequate for monthly dispensing; will we have enough supply to provide 3-month dispensing?

Programs should evaluate current stock (including buffer stock) to determine when replenishment stock is needed to provide MMD. This information should be communicated to interagency pediatric and supply chain ISMEs and to the OU's S/GAC Chair and PPM. PEPFAR-funded orders required for the remainder of CY 2020 should be made now.

In light of the shortage of LPVr 100/25 tablets, how can our program employ MMD for patients that require this product?

CLHIV who receive **LPVr 100/25** tablets can 1) be transitioned to a LPV/r 200/50mg formulation as soon as safely possible, or 2) receive a one month supply of LPV/r 100/25mg, or 3) depending on in-country supply, receive a 3-month supply of LPV/r 40/10mg pellets or granules. OUs are encouraged to reach out to HQ clinical and supply chain ISMEs with questions.

In the face of COVID-19 disruptions to PEPFAR-supported treatment programs, what is PEPFAR's guidance for children who are receiving EFV based regimens?

CLHIV who are already 20kg and receiving EFV should immediately transition to a DTG-based regimen. CLHIV who are <20kg and stable on EFV with virologic suppression can continue to receive EFV temporarily (during program disruption by COVID-19) but should be transitioned to DTG 50mg once they reach 20 kg.

TB-HIV FAQs in the setting of COVID-19

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How can we distinguish COVID-19 from tuberculosis (TB) in PLHIV?

TB and COVID-19 symptoms may overlap, and patients may be co-infected. Whether COVID-19 presents differently in HIV patients is unknown. COVID-19 typically presents more acutely. The cough for COVID-19 is not usually productive and fever is prominent. In contrast, patients with TB usually have a persistent cough of two weeks or more. Other TB-HIV associated symptoms include weight loss or persistent night sweats.

Programs should continue to screen, test, and think TB in high prevalence areas and consider testing for both TB and COVID-19 in PLHIV, especially in people presenting with fever and cough. COVID-19 screening is a more urgent screening and represents a higher risk to health care workers. COVID-19 screening should be performed first if indicated and available.

How will COVID-19 affect contact tracing & case-finding for TB?

Contact identification should be conducted at the first visit and patients should inform their identified contacts of their TB diagnosis and the importance of informing health care workers of their contact status should they present to a health facility for symptoms. Contact tracing may need to be deferred in the setting of COVID-19.

Community-based testing and active TB case finding strategies should follow local guidance on movement restriction and social distance measures to preserve the safety of healthcare workers and should be consistent with TB Programs' continuity of operations in setting of COVID.

How can we ensure continuity of services for TB-HIV treatment and TB Preventive Treatment in the context of COVID-19 disruptions?

- PLHIV on TB treatment should continue their treatment and avoid potential exposures to COVID-19 at health facilities.
- TB screening algorithms should incorporate COVID19 evaluation pathways. PLHIV screened for COVID-19 should be screened for TB. PLHIV screened for TB should be screened for COVID-19.
- Patients should be provided the full or remaining course of their drugs for TB-HIV or TPT at the next scheduled visit or sooner, if possible.
- Where possible, we recommend adhering to the usual schedule of evaluations for PLHIV with TB substituting telephonic consultations for in-person evaluations.
 - Specimen collection should adhere to national guidelines. Individuals should be provided with materials and instructions for sample self-collection in an outdoor or well-ventilated space.
 - Telephonic consultation during the intensive phase of TB treatment is critical and should focus on screening for signs of deterioration that would warrant a visit to a healthcare facility and on counseling regarding medication adherence.
 - At the end of the intensive phase of therapy a clinical visit may be warranted based on the clinical course.
- Further guidance may be found here:
https://www.who.int/tb/COVID_19considerations_tuberculosis_services.pdf

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How will COVID-19 epidemic affect HIV testing of individuals with presumptive TB?

All patients with suspected or confirmed TB should continue to receive HIV testing (see March 20, 2020 FAQ). Please refer to testing guidance for strategies and guidance for HIV testing in the setting of COVID-19.

How do we manage people with TB newly diagnosed with HIV in context of COVID-19 epidemic?

ART is usually started after TB therapy is underway. Consideration may be given to dispensing ART at the same time as the initial TB therapy with close telephonic consultation on when to start ART and for clinical follow-up to detect potential adverse events (e.g., IRIS-related symptoms). ART visits should be aligned with TB visits.

How will the COVID-19 epidemic affect TB testing of PLHIV with presumptive TB?

All PLHIV should be screened for both TB and COVID-19 symptoms at every visit, and if screen-positive for either or both diseases, appropriate respiratory specimen(s) collected for molecular diagnostic testing according to local policies and guidance. Note that presence of COVID-19 symptoms does not eliminate the need for TB testing, which should proceed according to current country and PEPFAR guidance. COVID-19 testing should take place according to local guidance and may be conducted concurrently with TB testing.

What about TB/HIV patients who become unwell at home?

TB-HIV patients who become unwell at home, should first contact the health facility by telephone to determine whether it is necessary to come into the facility. COVID-19 screening should be performed on the phone. Where an in-person visit is necessary, ensure understanding of procedures on arrival which should include a screen for COVID-19 and COVID-19 isolation where appropriate.

How will the COVID-19 epidemic affect people undergoing direct observed therapy (DOT)?

Individuals providing DOT should follow local guidance on social distance measures and restrictions on movement. The benefits of DOT must be balanced against the potential unintended exposure of healthcare workers. Telephone and/or video-assisted visits can help ensure adherence while abiding by social distance measures.

What infection control precautions should healthcare workers caring for TB-HIV patients take in the setting of COVID-19?

Programs should refer to WHO's Technical Guidance on Infection Control Measures in the setting of COVID-19: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance>

Addressing the triple risk of stigma & discrimination for patients with TB, HIV, and COVID-19

Stigma, discrimination, and social isolation are relevant for COVID-19, TB, and HIV. Programs should use lessons learned and ongoing efforts to reduce stigma for HIV and TB to also address and reduce the potential impacts of stigma and discrimination against patients with COVID-19.

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PEPFAR-supported cadres should follow host government guidance on home visits and avoid unnecessary interactions with clients in facilities and communities to reduce exposure to, and spread of, COVID-19.

How should PEPFAR-supported healthcare worker (HCW) staffing be modified to maintain essential HIV services?

PEPFAR programs should be prepared to manage staff through these challenging times, which could include quarantine, infection, increased caregiving responsibilities at home, absenteeism or social disruption. PEPFAR programs should stay abreast of health worker challenges and constraints and should track and report all changes made to HCW staffing due to COVID-19 to PEPFAR country staff.

PEPFAR-supported HCWs should be prepared to deliver the essential HIV services using service delivery teams that may be rapidly and regularly reconfigured in response to staffing shortages. Staff should be prepared for task-sharing of essential services where allowed, and work with MOH and policy makers to allow emergency task-shifting where formal task-shifting policies are not in place. PEPFAR staff whose regular services may have been paused or delayed (e.g., VMMC, roving TA) should be repurposed and redeployed to support essential HIV services. Refresh or build capacity in the new role through rapid training as necessary.

A critical element of the PEPFAR response to COVID is decentralized services. To this end staff may be repurposed to move services out of the facility and into the community wherever possible and safe. Staff may be reallocated to community-based ARV distribution for example. Where possible, digital applications or telehealth technologies should be utilized to remotely provide services. HCWs should be supported with the tools, airtime and data required, as well as training and scripts to use the technologies effectively and protect confidentiality and privacy. PEPFAR Technical Assistance (TA) providers should provide TA through telephone or digital applications in lieu of site visits.

What training is required to prepare PEPFAR HCW to respond to HIV in the context of COVID-19?

PEPFAR-supported HCWs should receive refresher training in Infection Prevention and Control (IPC) to protect themselves and HIV patients from COVID-19. While delivering HIV services, all HCWs should be equipped to provide COVID-19 risk communications to at-risk populations and PLHIV. As appropriate to their HIV service delivery role, HCWs should be trained to screen HIV patients for COVID-19 and refer as required for testing and treatment. HCW should be provided with in-country COVID guidance and case referral information (hotlines, facilities, etc.).

All training should be provided virtually using online platforms or printed job aids. Use international and national sources whenever possible. WHO is regularly updating available COVID-19 trainings at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/training/online-training>. Utilize digital applications such as WhatsApp, Facebook Messenger groups or the ECHO platform for regular and routine information sharing with HCW staff.

What actions should be taken to safeguard PEPFAR HCW, beyond PPE?

PEPFAR programs should follow host country and WHO guidance on minimizing HCW risk of contracting or spreading COVID-19. Identify every opportunity to support HCWs to do their jobs in a different, safer way. **PEPFAR programs should report all concerns regarding HCW staff safety and movement in**

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communities to PEPFAR country staff.

Decentralized Drug Delivery

Decentralized drug delivery systems offer the opportunity to reduce risk in the health care setting and are recommended for all programs. The guidance has been updated throughout to reflect this. See highlighted portions.

VMMC

There are minor updates to this section relating to NAE reporting.

March 27, 2020 Updates

How should OVC (and other PEPFAR-supported cadres) working with children and families in households, implement given COVID-19?

- ***PEPFAR-supported cadres should follow host government guidance on home visits and avoid unnecessary interactions with clients in facilities and communities to reduce exposure to, and spread of, COVID-19.***
- *Home visitors should help to ensure that all PLHIV have access to six months MMD, ideally through community-based distribution points, to maintain adequate supply of ARVs at home.*
- *To protect home visitors and beneficiaries, every effort should be made to use phone calls and/or text messages to communicate and avoid making a home visit.*
- *Home visitors who are at higher risk for severe COVID-19 (e.g., elderly, diabetic, or have other chronic conditions) should avoid conducting home visits. Home visitors should NOT visit beneficiaries if the visitor has any symptoms of acute illness, especially fever, cough, or shortness of breath, even if the symptoms are mild. Home visitors should NOT visit beneficiaries known to have a recent exposure to a person who tested positive for COVID-19 or is suspected of having COVID-19.*
- *To ensure safety and well-being of both home visitors and families, program staff should determine whether a home visit is absolutely essential.*
- *Many issues can be managed through counseling by phone. If unable to communicate via phone, situations that may warrant a visit include: 1) a critically ill beneficiary that urgently needs transport assistance to the clinic or hospital, 2) a child or adult exposed to physical harm, abuse or neglect requiring urgent attention, 3) CLHIV (or adult due to disability or other limitation) who cannot access ART and is in danger of treatment interruption.*
- *If the visit is deemed essential, ensure appropriate measures, including personal protective equipment (PPE) if available, are in place before, during, and after the visit and that both OVC staff and the client(s) consent to a visit. Once the family is stabilized, focus should then be to assist with 6mo MMD and/or drug pick-up from a community-based distribution point to ensure adequate supply of ARVs at home.*

Are we expected to continue SIMS implementation and reporting?

All PEPFAR programs are under Chief of Mission authority therefore country teams and implementing partners should follow Embassy Front Office direction on all programing that requires personnel movement. There are updated WHO guidelines and public health recommendations regarding personal

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safety to determine the feasibility of in-person site monitoring visits during the COVID-19 response. Please also refer to the Operational Issues and Infection Prevention and Control sub- sections of this guidance document. We recognize that SIMS implementation and reporting has, and will continue to be, affected during this time. Similar to guidance issued regarding MER, the SIMS Q2 reporting deadline has also been extended. **The SIMS FY20 Q2 import deadline is extended to May 29, 2020** (as per usual, this is one week prior to the quarterly DATIM data entry close deadline; now June 5 for FY20 Q2). Additional SIMS reporting guidance is forthcoming from SGAC_SIMS@state.gov

What if PEPFAR's recommendations for adapting HIV services in the context of COVID-19 do not align with local policy?

PEPFAR operates in partnership with the host government, and under Chief of Mission authority. PEPFAR country teams are urged to work promptly and closely with national governments to effect **temporary** changes in policy that will allow uninterrupted essential HIV services to ~~clients~~ **pediatric, adolescent, pregnant and breastfeeding women, and adults** while minimizing the recipients of care's interactions with health care facilities and health care workers during COVID-19.

Can clients initiating ART receive multi-month dispensing?

PEPFAR recommends that ALL PLHIV who are starting ART receive at least 3 but preferably 6 months of drugs. Phone or electronic follow-up may be helpful to assess and support adherence and to assess and manage side effects. Evidence from cohort studies indicate that <5% of clients initiating ART will require a change in ARV regimen in the first 6 months of treatment. Two forms of contact, as recommended in the COP 20 guidance, should be obtained in all PLHIV, especially in ART initiators.

Key Population Programming during the COVID-19 pandemic

Depending on how COVID-19 impacts your country, there may be significant interruptions in access to HIV services for key populations. This may lead to economic uncertainty, increased risk-taking behavior, further experience of stigma and personal violence. Community outreach and traditional peer outreach approaches will likely be disrupted and will need to be adapted based on the client's needs.

Prioritize Uninterrupted HIV Treatment Access, Clinical Care, and Support for Key Populations

- Services should be modified and decentralized so that all KPs can continue to access treatment, PrEP and viral load testing and other care through community platforms.
- Continued coordination and collaboration among community case management teams prioritizing virtual platforms to determine appropriate and needed differentiated services for KPLHIV

Testing, Prevention and PrEP Services

- Prioritize differentiated service delivery through community initiation and refill of PrEP and delivery of HIV testing including self-testing via mobile clinics, drop-in centers (DICs), and other community platforms or alternative arrangements for pickup or delivery of services
- Ensure peer outreach workers have enough supply of commodities and/or there are also community distribution points for commodities like condoms, lubricant and self-test kits.
- **Leverage Virtual Approaches:** Use of social media, phone, SMS, and alternative methods of communication by health care and peer workers may ensure critical services are continued.

Ensure Safety of Key Populations

- Programs should track reports of barriers to service delivery

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- Work with IPs and engage KP community-based organizations to provide basic communications materials including infection prevention
- Programs should ensure violence prevention mechanisms and referrals are functioning to track and link clients to needed services

How can Faith and Community leaders help with the multiplicity of challenges countries are facing due to the co-occurrence of HIV and a COVID-19 pandemic?

- Provide accurate and timely information from reliable sources about COVID-19
 - Use their influence to encourage their communities to follow government standards for social distancing and lockdowns
 - Understand that meeting in congregations must be postponed until after the epidemic has subsided
 - Encourage their congregations to maintain an adequate supply of ART
 - Support community networks
 - Protect the most vulnerable including children who may be exposed to violence.
- <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/healthy-parenting>

March 25, 2020 Updates

What is most important for PEPFAR teams to implement at this time?

Key principles for the PEPFAR response to COVID include continuity of ART therapy and accelerated decongestion of health facilities to minimize transmission of COVID-19 and protect PLHIV. The critical intervention for all programs and individuals is to accelerate and complete scale-up of 6-month dispensing of ART **and decentralized distribution**. If there are any barriers to 6-month MMD **(such as sufficient ARV availability)** implementation, programs should alert their S/GAC Chair and PPM **and USAID/SCH** immediately for advice and assistance **and should immediately quantify the increased ARV needs to scale 6MMD**. USAID is working with PSM to consider the additional quantities that may be required beyond the amount budgeted in COPs; and additional PEPFAR funding to roll out 6MMD at a broader scale will need to be considered by SGAC before additional TLD is procured to support a rapid implementation of 6 MMD.

Is the PEPFAR Quarter 2 reporting deadline still the same?

Recognizing challenges with site-level access in countries across the world, the PEPFAR Quarter 2 reporting deadline has been moved to Friday, June 5th. Detailed guidance is forthcoming from SGAC_SI. We will closely monitor PEPFAR program implementation in the ensuing weeks and provide updated guidance as needed for Quarter 3 reporting.

What should be done with TPT programs?

Tuberculosis preventive therapy remains a core HIV service and countries may continue their scale-up. A full course of TPT (INH or 3HP) should be dispensed. For those already on TPT, the remaining course of their TPT regimen should be given. Programs should ensure that systems are in place for adverse event monitoring whether via telephone, SMS, or electronically. Differentiated service delivery models may be

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helpful in this setting; adherence to infection control procedures is required.

What treatments are available for COVID-19?

Currently, there is no known effective treatment for COVID-19. We discourage the use of experimental therapies outside of registered clinical trials as they may be dangerous. Drug-drug interactions with ART and other HIV related therapies may pose particular risks for our PLHIV clients.

What about personal protective equipment?

There is currently a world-wide shortage of personal protective equipment (PPE). PEPFAR has not procured PPE in large quantities in the past and cannot currently ensure appropriate or adequate supply. We are therefore asking teams to seek alternative sources at this time. Current financial commitments will be honored. It is important that health workers providing ART services in areas impacted by COVID-19 use PPE to protect against self-exposure and transmitting to our highly vulnerable population. PEPFAR will work to gather and disseminate information about alternative sources or solutions for PPE as they become available.

Is there an update on index testing for key populations?

The evolving situation with COVID-19 may have implications for HTS implementation, monitoring and achieving HTS results, and teams are expected to operate under any COVID-19 related country guidelines as well as KP and HTS programming considerations below. However, given the progress made in recent months on ensuring HTS minimum standards through multiple processes, at this time, the previous halt on active index testing among key populations has been lifted. PEPFAR will work with country teams to ensure that either: (1) existing data confirm that current HTS provision at sites meets minimum standards or (2) sites are brought up to standards and assessed using vetted and valid tools. PEPFAR remains committed to ensuring all sites providing index testing services do so in a manner that meets established standards. Consult your S/GAC chair or PPM if needed.

Feedback/Question Submission: *As is feasible given your country situation, PEPFAR programs are requested to share new MoH guidance for HIV services in the COVID-19 context, incoming technical questions, as well as any solutions for PEPFAR programs in the context of COVID-19. Guidance that has already been issued should be shared for awareness; PEPFAR HQ would be happy to provide rapid input on guidance that is still in draft form. Please send these new MoH guidance documents directly to S/GAC by emailing them to Dr. Katy Godfrey gea0@cdc.gov, Teri Wingate gza2@cdc.gov, and Helina Meri MeriHD@state.gov, copying your Chair and PPM.*

March 20th Guidance

*In January 2020 a novel coronavirus, SARS-CoV-2, was identified as the causative agent of an outbreak of viral pneumonia centered around Wuhan, Hubei, China. The disease caused by this virus is called COVID-19. The WHO is reporting that there are now over **820,000** cases in **205** countries or territories.*

[<https://experience.arcgis.com/experience/685d0ace521648f8a5beeeee1b9125cd>] There has been widespread disturbance of international travel and shortages of medical supplies. In the areas hardest hit, medical facilities are overwhelmed in handling the large numbers of COVID-19 patients. During the COVID-19 pandemic, PEPFAR remains committed to supporting the provision of care and treatment of individuals

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with HIV while maintaining a safe healthcare environment for clients and staff. Deaths due to HIV and other co-morbidities must continue to be prevented during this time. In order to meet our commitment to continued care and treatment for PLHIV and the prevention of deaths among PLHIV due to HIV associated co-morbidities, PEPFAR is committed to supporting the host government response to the COVID-19 pandemic by leveraging existing PEPFAR resources, such that PLHIV have the best possible outcomes within the context of stretched healthcare systems. Overarching principles as well as specific technical guidance is provided for PEPFAR operational issues; prevention, testing, clinical services, supply chain, and laboratory activities; infection prevention and control; and budget guidance. This document will be updated routinely as the situation evolves.

Guiding principles for the provision of services in PEPFAR-supported countries during COVID-19 Pandemic

- **Protect the gains in the HIV response:**
 - Ensure continuous antiretroviral therapy (ART) provision to current recipients of care so that they have at least a three- and ideally a six-month supply of ART in order to maintain virologic suppression. ~~In areas where they do not already exist, dedicated and separate HIV clinic space should be carved at health facilities for protection of clients.*~~ (New wording was added below under “What changes should be considered for adjusting the model of service provisions for PLHIV?”.)
- **Leverage PEPFAR-supported systems and infrastructure:**
 - Utilize lab and surveillance systems and capacity to test for COVID-19.
- **Reduce transmission of COVID-19:**
 - Protect front line health care workers.
 - Reduce non-essential exposure of staff and clients to health care settings which may be both overburdened and potential sources of risk.
 - Note: this may require modification and/or temporary suspension of non-essential services.
- **In consultation with host governments, PEPFAR Operating Units (OUs) have flexibility to determine how best to continue to serve clients with HIV prevention and treatment services in areas affected by COVID-19:**
 - It is understood that scale-up of HIV prevention and treatment services may be delayed, given the COVID-19 pandemic; but we must innovate and adapt to local needs to try to maintain services, continue operations and reporting.

Operational Issues

How will operations at PEPFAR be affected and what measures should be taken to prevent disruptions?

- Social distancing measures including quarantine may result in disrupted operations due to travel restrictions and fragile communications networks outside of the larger cities. PEPFAR country teams
- should develop plans to stay in communication with headquarters, and with implementing partners who may be most affected.

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- Implementing partners should evaluate staff and supply resources that normally support PEPFAR/HIV services but that may be necessary to support COVID-19 control and treatment activities, after discussion with the PEPFAR team. Any requests to utilize resources that support HIV services but also respond to COVID-19 cannot be undertaken by an implementing partner without first consulting Agency grants management officers and receiving written authorization to do so. Agencies at Post must, in turn, consult with the S/GAC Chair with copy to SGAC M&B@state.gov ahead of granting approval for such activities.

~~Further guidance about measures in healthcare settings is available here-
<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html>~~

Prevention Activities

How will VMMC services be affected?

New VMMCs may be delayed or paused if guidance around mass gatherings renders them impractical. ~~New voluntary medical male circumcisions may be delayed or paused if guidance about mass gatherings cannot be followed.~~ Post-operative follow-up should continue for circumcisions that have already occurred with consideration given for telephonic consultation as an initial screening, before an in-person visit. We acknowledge that prevention services for men may be impacted by COVID- 19.

Should country teams continue reporting VMMC Notifiable Adverse Events and conducting investigations?

Teams should continue reporting NAEs as they normally would. If guidance around travel/stay-at-home orders makes the investigation of NAEs impossible, please include that information in the initial notification email to VMMC_AE@state.gov. **Investigations of any cases involving the death of a client should continue as normal to the extent possible.** Country teams should reach out to VMMC_AE@state.gov for any further guidance as needed

How will cervical cancers screening services be affected?

Cervical cancer screenings conducted outside of same-day and same-site ART clinical service visits should be limited to decrease exposure to health centers. Screening done as part of a routine ART visit may continue. Women undergoing evaluation and treatment for high grade lesions should continue with their recommended medical management. This will be reviewed in June.

How will the key population and DREAMS activities be affected?

With respect to prevention activities for KP and DREAMS beneficiaries, planning for smaller gatherings should begin. Group-based activities should follow local guidelines for mass gatherings (e.g. community mobilization and norms change sessions, parenting sessions, and 'safe space' sessions). If multiple groups are meeting concurrently in a shared space, teams/partners should be sure that there is enough time and space between groups so that they are still adhering to the local mass gathering guidance. For DREAMS specifically, if possible, country teams should consider temporarily moving safe spaces that are currently held in facilities into community spaces identified by AGYW and mentors. If this is not possible, teams/partners may need to consider postponing safe spaces meetings until guidance allows for them to begin again. Social media may be a useful alternative platform to maintain connections between AGYW and mentors (but should not be used for delivery of curriculum-based interventions). Additionally, where feasible and appropriate, facility-based DREAMS services should be offered in the community with appropriate social distancing.

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How will PrEP be affected?

For individuals already on PrEP, a 3-month ~~prescription~~ **supply of PreP medication** should be given. Any interim or follow up visits to assess side effects should be done by telephone, SMS, internet, or e-mail if possible **(with agreement of clients)**. Teams are encouraged to immediately calculate any increase in PrEP that would be required to dispense 3 months' worth of PrEP.

Community distribution and adherence support in small groups (less than 10 people present at a time) for PrEP may help support people and would not be a burden on the health care system. Adherence group meetings over the phone and use of SMS to send reminders is suggested as well. **It is suggested that decentralized drug distribution approaches be considered for PrEP that include: peer home delivery, scheduled community or private pharmacy pick-ups, distribution through pop-up pharmacies (that dispense other products such as products for hypertension, diabetes, HIV self tests, etc.).** Decentralized approaches can be used whether dispensing a monthly or 3-month supply. Note that it is up to the provider and client to decide how many months to dispense according to the needs of the client, and this can be done at any visit, including the first. As multi-month dispensing of PrEP occurs, it will be important to notify supply chain colleagues to ensure adequate supply planning.

HIV Testing

How will HIV testing activities be affected?

HTS Programming Considerations

All efforts should be made to support community social distancing and reduce contact of well persons with health care settings during COVID-19 period of risk. Plans should be in place to adapt programming should service be disrupted. We acknowledge that everyone who needs an HIV test may not get tested and target achievement may be impacted by COVID-19.

Potential issues/responses include:

- Adapting HTS programming to government directives or policies on social distancing.
- Maximizing use of self-testing outside of the clinic setting **(including providing self tests through decentralized distribution approaches such as: peer home delivery, private or community pharmacies, etc.)**
- Prioritizing clinical-based HTS for those most in need:
 - Testing in ANC
 - Diagnostic testing for individuals presenting (or admitted) to facilities with illness suspicious for HIV infection (Diagnostic testing)
 - Individuals with TB, STIs, malnutrition
 - Early infant diagnosis (EID) detection
 - Partner/index/family testing may be offered for individuals presenting at facilities (passive testing),
 - Testing in KP programs if ongoing and not facility based.
- HRH (including lay counselors/testers) may be impacted, reducing capacity from those affected by COVID-19
- HTS should not take place where adequate PPE is not available, which is routine guidance (e.g. gloves)
- For RTK implications, please see below Supply Chain section

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Provision of Clinical Care

How will clinical services for PLHIV be affected?

Guidance for continuation of essential medical service may be found here

<https://www.who.int/publications-detail/responding-to-community-spread-of-covid-19>. Ensuring and maintaining HIV viral load suppression should be considered an essential medical service for PLHIV.

How can the impact of COVID-19 be minimized for PLHIV supported by PEPFAR?

The critical intervention for all programs and individuals is to accelerate and complete scale-up of 6-month dispensing of ART **and decentralized distribution**.

What changes should be considered for adjusting the model of service provisions for PLHIV?

- The overarching goal is to minimize patient contact with health facilities and reduce the burden on these facilities.
- Health facilities should optimize clinic spaces in order to minimize potential exposure to COVID- 19. Individuals with proven or suspected COVID-19 should be separated from where care is provided to other clients. Dedicated HIV clinic spaces where they do not already exist may be useful in accomplishing this goal.
- Through phone calls or SMS, facilities staff should proactively communicate with HIV clients using positive messaging about the need to stay healthy.
- Facilities should maximize convenient six-month refills where stock is available in the country pipeline. Supply plans should be reviewed immediately to ensure any changes to scale 6MMD rapidly are immediately placed as orders.
- Clients should preferentially receive their drug supplies outside of the health facility*. These options could be used for dispensing ARV for any duration (for 1 month, 3 month or 6 month pick-ups), PrEP, HIV self-tests and other medicines already being supplied for chronic conditions (including drugs for hypertension, diabetes, etc). Decentralized distribution approaches include:
 - Home deliveries: through peer-run groups OR private delivery mechanisms that maximize social distancing and respect clients privacy.
 - Community or private pharmacies: with scheduled pick-up times to maximize social distancing.
 - Pop-up pharmacy: that provide additional infrastructure in remote areas outside hospital or clinic settings with pick-up windows that are configured to ensure social distancing.
 - Automated lockers: provide additional infrastructure outside hospital or clinic settings for drug pick-ups.
 - Community pickup: through community structures such as schools, churches/FBOs, post offices or KP-focused sites
- Where countries are moving towards limiting movement, due to COVID, countries will need to work with law enforcement and other officials to:
 - Ensure importation and transport of health commodities isn't interrupted
 - Ensure that decentralized distribution approaches are permitted
- If OUs have significant movement restriction and/or high absenteeism amongst HCW, alternatives to face-to-face care provision should be considered, including the use of phone consultations.

~~*See Decentralized Drug Distribution strategic guide~~

What is known about how COVID-19 affects PLHIV?

The evidence on the impact of COVID-19 amongst PLHIV is still scarce. There is currently no direct

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evidence that people with HIV are at higher risk of COVID-19, or of severe disease if affected. As more data becomes available from regions of high prevalence, we will continue to update the field on the effect of COVID-19 on PLHIV. HIV virological suppression is a critical intervention that improves the health of all PLHIV.

How can the most vulnerable patients be protected?

Older age and presence of uncontrolled comorbidities such as hypertension, diabetes and heart disease pose a higher risk for COVID-19 morbidity and mortality. All efforts should be made to streamline health services for older individuals living with HIV (>age 50) PLHIV with advanced disease, and those with co-morbidities. Programs should be sensitive to the medication needs of these individuals, seek methods to reduce the number of times these individuals require being in health care facilities.

What is the role of ARVs in the treatment of COVID-19?

There is no evidence that DTG- and EFV-based regimens which account for >90% of all ART in PEPFAR-supported program, have any activity or role in treating COVID-19 infections. Lopinavir/r is being investigated for use in the setting of COVID-19; there is no conclusive evidence at present supporting its efficacy. A recent clinical trial failed to show a benefit². Accurate messaging to prevent diversion of ARVs should be provided.

What changes in the clinic flow should be made to protect patients and HCW?

Waiting rooms can be a source of transmission for respiratory illness. Despite measures to maximally reduce the number of PLHIV coming for in-person facility visits, some visits will still be necessary. Consider staggering clinical appointments to avoid crowding and streamlining clinic flow so PLHIV do not interact with multiple HCW (e.g. avoiding multiple points of contact between PLHIV and HCW). Optimizing space to reduce close contact may be helpful. HIV patients should be seen in clinics that are dedicated spaces for HIV treatment services.

How will TB and TPT services be affected?

For individuals already on TB or TPT regimens, please ensure they have the remaining doses needed to complete a full course of treatment. Ensure that side effect monitoring can be done via telephone, SMS, or electronically. DSD models, if in place may be utilized for community distribution and adherence support as long as they adhere to social distancing policies and guidance within the country/district.

Supply Chain for ARVs

Will the drug supply chain be affected?

*The ARV manufacturers (largely based in India) are reporting having sufficient active pharmaceutical ingredients (API) to continue production of formulations, specifically TLD and other ARVs. GHSC-PSM is exploring all modes of transportation to reduce the transit time and prepone the delivery of orders. S/GAC recommends that programs continue to scale up six-month MMD in order to ensure patients have a sufficient supply of ARVs in the event that patients are unable to visit the clinic. **Teams need to immediately let S/GAC and USAID's SCH Division know if TLD in current supply plans cannot support 6MMD at a broader scale.***

² Cao B, Wang Y, Wen D, Liu W, Wang J, Fan G et al. A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19. 2020. doi:10.1056/NEJMoa2001282.

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What changes may be anticipated for the supply chain of drugs?

As the COVID-19 pandemic continues to evolve S/GAC, USAID, CDC and GHSC-PSM have taken steps to monitor the situation as it pertains to availability of ARVs and other drugs essential to the HIV response. Because of anticipated delays USAID has instructed the Missions to place orders **one month earlier than normal lead times would suggest. As mentioned above, additional stock may be required to activate 6MMD at a wider scale and commodity needs above COP19 and COP20 plans should be discussed with USAID and PSM immediately.**

What should be done to prevent country-level drug shortages?

Consider the following interventions:

- Substituting products/formulations where necessary.
- Ongoing supply plan and inventory data (PPM/R) review to identify and respond to urgent need
- **Decentralized distribution approaches (as highlighted above) that include: Home deliveries, community or private pharmacies, pharmacy in a box and automated lockers.**
- Order staggering to prevent delivery delays
- Prioritization exercises across Task Order and as feasible across procurers to ensure that the most urgent need is met (across products, across countries)
- Reallocation of urgently needed orders to less impacted suppliers, as warranted and feasible

Laboratory Operations and Supply Chain For Laboratory

How has COVID-19 affected the supply chain of laboratory products and what measures should be taken to minimize its impact?

There are current delays for rapid test kits (RTKs) either manufactured in China or relying on key starting materials from China, and Asia, more broadly. Delays or pricing increases are being tracked and communicated as they arise. Current guidance is to place orders for laboratory commodities and RTKs **one month** earlier than normal, to account for potential shipping delays.

What is the overlap between viral load testing and SARS-CoV-2 testing, since they are both PCR-based?

At present, most laboratories in the Africa region are using instruments and reagents for SARS-CoV-2 testing that are different from those used for HIV viral load and EID testing; however, SARS-CoV-2 testing options are evolving rapidly and commonly used HIV viral load and EID instruments are anticipated to be coming online for SARS-CoV-2 in the short to medium term.

How will SARS-CoV-2 testing impact HIV VL testing?

OUs should anticipate increased use of common consumables and PPE for COVID-19 and HIV-related testing in laboratories and anticipate and plan for diversion of or reductions in laboratory staff and other HRH available for HIV (VL/EID) testing due to COVID-19. Laboratories should prioritize testing based on local requirements. For HIV laboratory testing, EID and viral load services for children, PBFW, and adults with documented non-suppression on their last VL result should be prioritized.

What measures should be taken to ensure stocks of laboratory supplies?

OUs should update current stock counts at national and subnational levels and forecast for additional consumable needs to accommodate increases in COVID-19 testing. It is recommended that orders be placed at least one month in advance to reduce the risk of shipping delays resulting in stock outs.

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Is there a plan to use HIV VL/EID platforms for SARS-CoV-2 testing?

On Friday, March 13, the Roche SARS-CoV-2 Test received FDA emergency use authorization (EUA) and other manufacturers are developing COVID-19 tests that may be run on existing HIV VL/EID instruments.

What procedures should be carried out if testing for SARS-CoV-2 and HIV VL/EID are conducted in the same laboratories?

In PEPFAR supported laboratories running COVID-19 and HIV-related testing on the same instrument, SOPs should be developed to account for prioritization of testing (e.g., COVID-19, EID, VL).

Tracking Supply Chain Impact

How will supply chain for COVID-19 be tracked?

*GHSC-PSM is in the process of developing a **COVID 19 Impact Dashboard**, which will allow Mission supply chain staff to track the impact of COVID-19 on their orders. Additionally, GHSC-PSM is*

*developing a **Market Risk Map** by commodity portfolio to assess the long-term impact commodity portfolio to assess severity of the risk, probability of the risk, and timing of the potential risk to help inform our short and long-term mitigation strategies*

How will USAID and GHSC-PSM Mitigate Risk?

- *Early Identification of Delayed and At-Risk Orders*
- *Bi-weekly order status reports from all suppliers with supplemental calls as needed*
- *Ongoing monitoring of key raw material export data*
- *Ongoing market assessments to identify capacity constraints*
- *Ongoing updates on sampling restrictions and communications with QA labs*
- *Exploring alternate shipment modes to reduce delays*
- *Coordination meetings with WHO Access to Medicines and Health Products, and the Global Fund*

Infection Prevention and Control

What measures should be implemented to reduce COVID-19 exposures in the healthcare setting?

- *The basic principles of IPC and standard precautions should be applied in all health care facilities and are critical to containment of SARS CoV-2.*
- *Health care facilities visits should be limited to those that are medically essential*
- *All facilities should have a designated focal point to oversee and monitor infection prevention activities; this individual should be supported to provide the basic principles according to WHO guidance which include:*
 - *Written procedures for identifying and managing clients and staff with potential COVID- 19 exposures or illness;*
 - *Systematic triage to identify ill persons;*
 - *Strict adherence to hand hygiene and respiratory hygiene;*
 - *Medical masks to be used by patients with respiratory symptoms;*
 - *Prioritization of care of symptomatic patients*
 - *When symptomatic patients are required to wait for services; ensure they are placed in a separate waiting area.*

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- *Appropriate supplies to allow implementation of contact and droplet precautions for all suspected COVID-19 cases;*
- *Strict protocols for routine cleaning and disinfection of medical equipment and environmental (especially “high touch”) surfaces*
- *Education and training of staff regarding IC precautions for COVID-19*
- *Airborne precautions are recommended only for staff performing aerosol generating procedures. These procedures include tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, and bronchoscopy*

~~*In areas where they do not already exist, dedicated and separate HIV clinic space should be carved at health facilities for protection of clients.* (moved up in the March 20 guidance with updated wording).*~~

Details can be found here:

[https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-\(ncov\)-infection-is-suspected-20200125](https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125)

Supply Chain for Personal Protective Equipment (PPE)

Requirements for PPE can be found here:

https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1-eng.pdf

The Chinese government has taken control of medical PPE supply for priority use in Wuhan and has disallowed export of these products. We will continue to monitor China’s export restrictions for changes in this policy.

Alternative PPE products are available from Europe, but these products may be more expensive to procure. GHSC-PSM is pursuing alternative products from Europe and delays of 6 weeks are expected. PSM is currently reviewing country PPE orders and budgets to mitigate these delays. Minimum delays of 6 weeks are expected but may change as the situation evolves.

Alternative products may be available from Europe but are more expensive. GHSC-PSM is reviewing country urgency and budget to mitigate these delays.

Budget Guidance

Please coordinate with your agency financial POCs for how to address any budget implications of implementing this guidance.

~~*Adaptation of PEPFAR programs to ensure HIV patients receive the services they need in the context of COVID-19 is expected to occur within the confines of existing, approved COP19 budgets and mechanisms, such that operational plan updates are not required.*~~

~~*Should a programmatic adaptation arise that would necessitate an operational plan update or otherwise require special consideration, please reach out to the S/GAC Chair and PPM and SGAC_Budget@state.gov with a description of the situation you are seeking clarity on. SGAC M&B will coordinate with the Chair/PPM and the SGAC FO to resolve the issue. Please do not initiate an OPLU before receiving feedback on issue.*~~